Remarks

In the outstanding Official Action, the Examiner:

(1) noted that Applicant has not filed a certified copy of the foreign priority document;

(2) acknowledged Applicant's election without traverse of Group I, claims 1-8;

(3) objected to the specification as failing to provide proper antecedent basis for the claimed subject matter, making specific reference to the gel being in the form of a microgel;

(4) rejected claims 1-5 and 8 under 35 USC 102(b) as being anticipated by Luissi et al. ("Luissi");

(5) rejected claims 1-4, 6 and 8 under 35 USC 102(b) as being anticipated by Marchant et al. ("Marchant");

(6) rejected claims 1-5 and 8 under 35 USC 102(b) as being anticipated by Wokalek et al. ("Wokalek");

(7) rejected claims 1-5 and 8 under 35 USC 102(b) as being anticipated by Pfirrmann et al. ("Pfirrmann"); and

(8) rejected claims 1-3, 7 and 8 under 35 USC 102(e) as being anticipated by Young et al. ("Young").

With respect to Item 1 above, Applicant intends to submit a certified copy of the foreign priority document shortly.

With respect to Item 2 above, no response appears necessary.

With respect to Item 3 above, Applicant has now amended the specification in order to provide a proper antecedent basis for claim 4. Applicant believes that this amendment should be sufficient to overcome the Examiner's objection to the specification.

In response to Items 4 through 8 above, Applicant has now canceled claims 2 and 8 without prejudice and subject to Applicant's right to pursue these claims in related applications, amended claims 1 and 3-7, and added new claims 11-20.

Claim 1 has now been amended to call for a composition comprising a thixotropic gel and an antimicrobial agent contained in the thixotropic gel. Furthermore, the amended claim now makes it clear that the thixotropic gel is characterized by:

(i) easy flow under the shear forces imparted by a conventional medical syringe such that the composition may be instilled into, and withdrawn from, a hemodialysis catheter using such a conventional medical syringe;

(ii) sufficient cohesiveness such that, when the composition is moved through the lumen of a hemodialysis catheter using a conventional medical syringe, the composition advances through the lumen as a cohesive rod-shaped mass; and

(iii) when the composition is disposed within the lumen of a hemodialysis catheter which is installed in the vascular system of a patient, the composition remains in the lumen substantially without leakage. In addition, the amended form of the claim also calls for the thixotropic gel to be biocompatible and biodegradable in blood.

Applicant has reviewed the cited references. None of the references relates to a catheter lock and, accordingly, none of the references teaches a composition similar to Applicant's invention as now claimed.

Luissi, Wokalek, Pfirrmann and Young all fail to disclose a thixotropic gel. This may not be significant given the applications intended by Luissi, Wokalek, Pfirrmann and Young. However, it is a critical omission when one considers the application intended by Applicant, i.e., a catheter lock. This is because it is the thixotropic nature of the Applicant's gel which makes it practical to use the composition in a hemodialysis catheter in accordance with current industry practice, e.g., instilling and removing the catheter lock using conventional medical syringes.

Marchant makes two references to thixotropic: in the last table of Example 5, and in Example 11. However, Marchant

contains no teaching or suggestion of using his composition as a catheter lock. Consequently, Marchant contains no teaching or suggestion as to how the thixotropic nature of the composition must be coordinated with industry standard apparatus (e.g., conventional medical syringes) so as to make it practical to use a gel in a catheter lock application.

It should be further noted that Marchant discloses a bioadhesive polymer composition. While the adhesive characteristics of the Marchant composition may be very desirable for Marchant's intended applications, they make it totally impractical to use the Marchant composition in a hemodialysis catheter - it could inhibit catheter instillation and removal and, perhaps even more significantly, it could block a blood vessel (i.e., cause a stroke) in the event that the composition should become free in the bloodstream. Thus, Marchant is not believed to disclosed or render obvious the claimed invention.

New claims 16-20 have been added to further claim the present invention. Specifically, new claim 16 calls for a novel system comprising a hemodialysis catheter and the novel catheter lock composition. New claim 17 calls for a novel method for providing microbe-free access to the vascular system of a patient. New claim 18 calls for a novel method for providing a

microbe-free seal for a hemodialysis catheter installed in the vascular system of a patient. New claim 19 is dependent on claim 1. New claim 20 is dependent on claim 16. None of these claims are believed to be anticipated by, or rendered obvious by, any of the references of record.

On account of the foregoing, Applicant submits that claims 1, 3-7 and 11-20 are in condition for allowance. Early and favorable reconsideration is therefore respectfully requested.

In the event that any additional fees may be required in this matter, please charge the same, or credit any overpayment, to Deposit Account No. 16-0221.

Thank you.

Respectfully submitted,

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